VIRGINIA BOARD OF PHARMACY
6603 West Broad Street, 5th Floor
Richmond, Va. 23230-1712
Telephone (804) 662-9911
FAX: (804) 662-9313
email: pharmbd@dhp.virginia.gov
http://www.dhp.virginia.gov/pharmacy/default.htm

APPLICATION INFORMATION FOR THE PHARMACIST EXAMINATION

The application must be completely executed. Incomplete applications will be promptly returned.

Practical Experience Requirements:

An applicant shall accumulate a minimum of 1,500 hours of practical experience to include no less than 300 hours in the area of compounding and dispensing. For purposes of this regulation, credit will not be given for more than 50 hours in any one week. Students having graduated from an approved school of pharmacy prior to January 1, 2003 shall have gained at least 1,000 hours of practical experience. The 1,500 hours may include hours gained within an approved school clerkship program. However, at least 300 hours of the 1500 hour requirement shall be gained outside of a school of pharmacy practical experience program. All practical experience hours used in meeting this requirement must be gained after the first professional year of pharmacy school and within the United States.

Certificates of Practical Experience:

- Affidavits of experience gained in Virginia must be signed by the supervising pharmacists, and attached to the application (if not previously submitted to the Board).

- Certificates or documentation of practical experience gained in another state must be certified by the Board of Pharmacy in that state and must be received by this Board directly from that state. This documentation must show actual dates of employment, total hours worked, place of employment and name of supervising pharmacists, and the certifying Board shall verify current, unrestricted licensure status of the supervising pharmacists.

No documentation certifying hours earned through an approved college clerkship program is needed in addition to the information required on the application under "College Affidavit."

Application Fee: ONE HUNDRED EIGHTY DOLLARS ($180.00)

MAKE CHECKS PAYABLE TO: "Treasurer of Virginia"

Mailing Address for Completed Application:

Virginia Board of Pharmacy
6603 West Broad Street, 5th Floor
Richmond, Va. 23230-1712

STUDY GUIDE IS ATTACHED TO THIS DOCUMENT

Virginia Board of Pharmacy

FEDERAL AND STATE DRUG LAW EXAMINATION HANDBOOK

January 2006

Table of Contents

Contacts

All questions about the FSDLE written examinations should be directed to:

Comira
1801 Murchison Drive, Suite 288
Burlingame, CA 94010
Phone: 800-947-4228
Fax: 650-692-9537

Questions about licensing should be directed to:

Virginia Board of Pharmacy
6603 West Broad Street, 5th Floor
Richmond, VA 23230-1712
Phone: 804-662-9911
Fax: 804-662-9313

FSDLE GUIDE AND INFORMATION

This Handbook will provide you with the necessary information regarding scheduling your Virginia Federal and State Drug Law Examination (FSDLE).

Purpose of Examination

Pharmacists, among all the health professionals, are entrusted with the most important drug control responsibilities. To ensure entry-level competence, the Virginia Board of Pharmacy administers a combined federal and state drug law examination. A single examination tests candidates' knowledge of Federal Drug Law and Virginia Pharmacy Law and Regulations.

Scheduling your FSDLE Exam through Comira

The state of Virginia has contracted with Comira to conduct its examination program. You may be able to register for your FSDLE Exam at any of Comira's testing locations. Locations can be found by visiting their website at www.comiratesting.com or by calling their toll free registration number at: 800-947-4228 between 9 a.m. and 8 p.m. (Eastern Time) Monday through Friday and between 11 a.m. and 3 p.m. on Saturday.

Appointments are available Monday through Friday at most testing centers with some weekend availabilities. Comira recommends scheduling your exam at least 3 days prior to your exam date.

Same-day walk-in registration: If an appointment time is available, you can register at the site and take your test immediately.

Canceling or rescheduling your exam. Comira requires a 24-hour cancellation or rescheduling policy. In the event of an emergency on the day of the exam please contact both the Testing Location and Comira. Failure to notify Comira in a timely manner may result in forfeiting your exam fee.

At the time of registration you will be asked a series of questions:

- When – **The day and time you wish to take your exam.**
- Where – **The location of the Testing Center.**
- Payment – **You may be able to pay the $100 Testing Fee with a personal credit card over the phone. For other means of payment contact the Comira's Registration Department.**
- Full Legal Name **– Your official name on record given to the Virginia Board of Pharmacy.**
- Social Security number or Virginia DMV control number – **This is your personal identification number that will be used by both the Virginia Board of Pharmacy and Comira.**

Comira's testing computers are secured and protected as U.S. Government *For Official Use Only* information. All FSDLE data is the property of the Virginia Board of Pharmacy and may not be used for any other purpose than authorized by this order.

Format of the FSDLE and Fees

The exam consists of 100, multiple-choice questions. It includes several simulations of prescriptions, labels, and refill records. Only one correct response exists for each question. Candidates are given two hours for its completion. A passing score of 75 is required. The fee for this exam is $100 and payable to Comira at the time of registration.

Taking the Examination

Your examination will be administered via computer at a Comira Testing Center. You should arrive 15 minutes prior to your schedule appointment to allow you to sign in, verify your Identification, and allow you to familiarize yourself with the software. You do not need any computer experience or typing skills to take the exam. You will have available to you a demo test that will familiarize you with the testing software and its features. This demo test does not count toward the time allowed to take your FSDLE exam.

Identification

Prior to test administration you must provide the testing center positive identification. The identification presented must include a current photograph, full legal name as submitted during registration, signature, and social security number or Virginia DMV control number. This information may be presented in more than one form of identification.

Acceptable forms of Identification include driver's licenses, government identification cards, passports, alien residency cards, and military identification.

Failure to provide appropriate identification at the time of examination will be considered a missed appointment.

For additional information on identification and authorization please contact Comira before scheduling your exam.

Special Accommodations

Should you require special accommodations please contact the Virginia Board of Pharmacy prior to scheduling your exam.

Survey

At the end of your exam you will be asked a series of questions regarding your overall testing experience. All completed surveys are forwarded to the Virginia Board of Pharmacy and Comira for further evaluation.

Exam Results

At the end of your exam you will be issued a pass/fail letter. You will then sign out on the daily sign in/out log. If successful in passing, you will receive your license to practice from the Virginia Board of Pharmacy within one week. The pass letter is not considered authorization to begin practicing.

Retesting

If you fail the exam you may retake it after a 5-day waiting period. Please contact Comira to schedule your retake. You will be required to pay the examination fee of $100 each time the test is administered.

How to Use This Study Guide

Be sure to obtain all references listed for the examination. The supplemental references listed herein are highly recommended. You should become thoroughly familiar with the study guide. To prepare for the examination the candidate is referred to the behavioral objectives for a description of the exam's content.

You should recognize that the list of competencies or behavioral objectives in this guide specifies the title, chapter, and section number of the law and regulations for which test questions exist. Only specified sections within each chapter of the law are tested. While emphasis should be placed on the sections specifically indicated, it is recommended that you master all the relevant law and regulations for full comprehension.

The examination covers all state and federal law and regulations required for competent entry-level practice. Since much of state drug law duplicates federal law, emphasis is placed on state law, and where possible, information is referenced to state law rather than to federal law. Specific mention of titles, chapters, and sections of federal drug law is limited to those areas of federal law not already covered within the body of state specific law.

It is recommended that you supplement your study of pharmacy law by reading additional text books, journals, and related academic course materials.

Recognize that laws, rules, and standards are modified from time to time, and it is your responsibility to keep your knowledge current during the course of your future professional practice.

Candidate Study Guide

Federal and State Drug Law Exam (FSDLE)

List of References

1. *Code of Virginia*
   Pharmacy, General Provisions
   (54.1-3300 through 54.1-3319)

2. Board of Pharmacy Regulations
   (18 VAC 110-20-10 through 18VAC 110-20-680)

3. *Code of Virginia*
   Drug Control Act
   (54.1-3400 through 54.1-3472)

4. *Code of Virginia*
   Crimes Involving Health & Safety
   (18.2-247 through 18.2-265)
   (18.2-8 through 18.2-16)

5. *Code of Virginia*
   Department of Health Professions
   General Provisions
   (54.1-2400 through 54.1-2409)

6. *Code of Virginia*
   Department of Health Professions
   (54.1-2500 through 54.1-2510)

7. *Federal Controlled Substance Act*
   (21 USC 801 et seq)
   (21 CFR 1301 et seq)

8. *Federal Food, Drug, and Cosmetic Act* (FDCA)
   (21 USC 301 et seq)

9. *Prescription Drug Marketing Act* of 1987
   (21 USC 353)

Suggested Supplemental References

1. *Pharmacy Law Digest*
   Facts and Comparisons, Inc.
   111 West Port Plaza, Suite 400
   St. Louis, MO 63146-3098
   800.223.0554

Website Links

VIRGINIA BOARD OF PHARMACY: www.dhp.virginia.gov/pharmacy
Click on Laws and Regulations

UNITED STATES CODE: http://www.gpoaccess.gov/uscode/index.html

CODE OF FEDERAL REGULATIONS: http://www.gpoaccess.gov/cfr/index.html

Federal And State Drug Law Exam (FSDLE) Content Outline

1.	**OBTAIN AND MAINTAIN STATE LICENSE**		**16**
	A. Obtain, Renew, Maintain License	(2)	
	B. Standards of Conduct	(3)	
	C. Pharmacy Permits	(2)	
	D. Inspection Authority of Board and Police	(1)	
	E. Obtain DEA and FDA Registration	(6)	
	F. Comply with DEA and FDA Inspection and Enforcement Authority	(2)	
2.	**ORDERING, RECEIVING, AND MANAGING DRUGS**		**13**
	A. Order Schedule II-VI Drugs	(5)	
	B. Receive Schedule II-VI Drug Products	(4)	
	C. Inventory	(3)	
	D. Drug Disposal	(1)	
3.	**MAINTAIN INTEGRITY OF DRUGS AND DRUG PRODUCTS**		**12**
	A. Define Terms	(4)	
	B. Assure and Maintain Integrity	(3)	
	C. Returned Drugs	(2)	
	D. Repackage and Label Prescription Drugs	(3)	
4.	**SECURITY**		**13**
	A. Access, Storage, Security Schedule II-VI Drugs	(9)	
	B. Report Stolen or Lost Drugs	(4)	
5.	**REVIEW PRESCRIPTIONS**		**22**
	A. Receive Prescriptions and Orders	(8)	
	B. Review Prescriptions		
	1. Review for Legality	(8)	
	2. Review for Required Elements	(4)	
	3. Conduct Drug Use Reviews	(2)	
6.	**DISPENSING AND DISTRIBUTING**		**24**
	A. Dispense Drugs Pursuant to a Prescription	(15)	
	B. Dispense Drugs Using Unit Dose System for Hospital or LTC	(3)	
	C. Dispensing and Distributing by Other Methods	(5)	
	D. Dispense Medical Devices	(1)	
		Total:	**100**

VIRGINIA DRUG LAW EXAMINATION

I. LICENSING/REGISTRATION

A. OBTAIN, RENEW, AND MAINTAIN PHARMACIST LICENSE

1. Describe the requirements and procedures involved in obtaining and renewing a Pharmacist license (18 VAC 110-20-20, 18 VAC 110-20-30, 18 VAC 110-20-40, 18 VAC 110-20-50, 18 VAC 110-20-60, 18 VAC 110-20-70, 18 VAC 110-20-80)
2. Explain the requirements for completing continuing education and maintaining documentation (54.1-3314.1(A-I), 18 VAC 110-20-80, 18 VAC 110-20-90, 18 VAC 110-20-100)
3. Explain dispensing activities which are restricted to pharmacists (18 VAC 110-20-270, 54.1-3320)
   a. Explain limitations on use of non-pharmacist personnel (18 VAC 110-20-270, 18 VAC 110-20-111, 54.1-3320, 541.-3321)
   b. Explain requirements and responsibilities for supervising intern practical experience (18 VAC 110-20-40(B)), 54.1-3320.
   c. Define the following terms:

1. Practice of Pharmacy	54.1-3300
2. Personal Supervision	18 VAC 110-20-10, 54.1-3300
3. Intern	18 VAC 110-20-40(A), 54.1-3300

B. MAINTAIN STANDARDS OF LEGAL AND PROFESSIONAL CONDUCT

1. Explain grounds for disciplinary action
   a. List the grounds for revocation or suspension of a pharmacist's license or of a pharmacy permit (54.1-3315, 54.1-3316, 54.1-2408.1, 54.1-2409)
   b. Define “unprofessional conduct” (54.1-3315)
   c. Recognize requirement to maintain patient confidentiality (18 VAC 110-20-380)
   d. Describe prohibited kickbacks, fee-splitting (18 VAC 110-20-390)

C. OBTAIN AND RENEW PHARMACY PERMITS

1. Explain the requirements and procedures involved in obtaining and renewing a pharmacy permit (54.1-3434, 18 VAC 110-20-20(D), 18 VAC 110-20-110, 18 VAC 110-20-120, 18 VAC 110-20-140, 18 VAC 110-20-150)
   a. File application and meet Board requirements to open a new pharmacy, change location of an existing pharmacy, move the location, or make structural changes to a prescription department (54.1-3432, 54.1-3434, 18 VAC 110-20-140, 18 VAC 110-20-150, 18 VAC 110-20-160, 18 VAC 110-20-170, 18 VAC 110-20-180, 18 VAC 110-20-190, 18 VAC 110-20-200)
   b. Describe required security, professional and technical equipment needed for operation of a pharmacy (54.1-3434, 18 VAC 110-20-150, 18 VAC 110-20-160, 18 VAC 110-20-170 18 VAC 110-20-180, 18 VAC 110-20-190, 18 VAC 110-20-200)
   c. Describe the requirements for display of a pharmacist license and a pharmacy permit (54.1-3430), 54.1-3314.
   d. Describe the responsibilities of the pharmacist-in-charge (54.1-3434, 18 VAC 110-20-450, 18 VAC 110-20-440, 18 VAC 110-20-110)
2. Explain the procedures for closing a pharmacy and appropriate disposition of drugs and records (54.1-3434, 54.1-3434.01, 18 VAC 110-20-130)
3. Explain when a separate out-patient pharmacy permit is required in a hospital (18 VAC 110-20-480)

D. COMPLY WITH THE INSPECTION AUTHORITY OF THE BOARD OF PHARMACY AND THE STATE POLICE

1. Describe powers of inspection and inspection procedures and access to records by board agents and state police (54.1-3307, 54.1-3308, 54.1-3405)
2. Describe access to prescription records during inspections (54.1-3405)

E. OBTAIN DEA AND FDA REGISTRATION

1. Determine the need for and describe the procedures involved in obtaining and renewing DEA registration (21 CFR 1301)
2. Determine the need for and describe the procedures involved in obtaining and renewing FDA registration (21 USC 360)
    a. Define the term manufacturing (DCA 54.1-3401, 21 USC 802(15), 21 USC 360
3. Explain the registration requirements for maintenance and detoxification treatment programs (21 CFR 291.505)
4. Explain the regulations governing discontinuance of practice (21 CFR 1301.52, 1307.21)
5. Explain the requirements for registration modification and transfer (21 CFR 1301.51 and 1301.52)

F. COMPLY WITH DEA AND FDA INSPECTION AND ENFORCEMENT AUTHORITY

1. Describe powers of inspection, inspection procedures, access to records by DEA and FDA agents, and rights of pharmacist (21 CFR 1316, 21 USC 360(h), 21 USC 374)
2. Understand the restrictions which are imposed on the hiring of persons having access to Schedule II-V controlled substances (21 CFR 1301.90)

II. ORDERING, RECEIVING, AND MANAGING DRUG INVENTORY

A. ORDER SCHEDULE II-VI CONTROLLED DRUGS

1. Determine the conditions for legally transferring Schedule II-VI controlled drugs between registrants (54.1-3414, 54.1-3415)
    a. Explain the limitations on transferring CS between registrants (21 CFR 1307.11-12)
2. Explain the use of official DEA order forms in ordering and transferring Schedule II drugs (21 CFR 1305)
    a. Definitions
    Official written order (21 CFR 1305)
    b. Identify who can execute DEA order forms (21 CFR 1305)
    c. Explain how to handle lost or stolen order forms (21 CFR 1305)
3. Explain the conditions under which drugs may be ordered or possessed in accordance with the Prescription Drug Marketing Act of 1987 (21 USC 353)

B. RECEIVE SCHEDULE II-VI DRUG PRODUCTS

1. Explain requirements for maintaining records of receipt for Schedule II-V drugs (54.1-3404(C), 18 VAC 110-20-240(A))
    a. Explain documentation of receipt of Schedule II drugs (21 CFR 1305.10)

C. INVENTORY

1. Perform inventory of Schedule II-V controlled substances (54.1-3404 (A, B, and E), 54.1-3434)
    a. Describe the inventory requirements for Schedule II-V controlled drugs, in terms of dates, required records, format, count requirements, filing, and newly scheduled drugs (54.1-3404, 18 VAC 110-20-240(A))

D. PROVIDE FOR PROPER DISPOSAL OF DRUGS

1. Properly dispose of Schedule II through V drugs (54.1-3417, 18 VAC 110-20-210)
    a. Identify the procedure for the destruction or disposition of unwanted Schedule II-VI controlled substances or their transfer upon discontinuance of business (54.1-3417, 18 VAC 110-20-130, 18 VAC 110-20-210)
    b. Explain record keeping requirements (54.1-3404(D), 18 VAC 110-20-210)
2. Explain the requirements for disposition of discontinued drugs for LTC facilities, to include records (18 VAC 110-20-530(7)(a-d))

III. MAINTAIN DRUG INTEGRITY

A. DEFINE THE FOLLOWING TERMS

1.	Prescription department	(18 VAC 110-20-10)
2.	Light resistant container	(18 VAC 110-20-10)
3.	Proprietary medicine	(54.1-3401)
4.	Storage temperature	(18 VAC 110-20-10)
5.	Tight container	(18 VAC 110-20-10)
6.	Unit dose container	(18 VAC 110-20-10)
7.	Unit dose package	(18 VAC 110-20-10)
8.	Unit dose system	(18 VAC 110-20-10)
9.	Well-closed container	(18 VAC 110-20-10)
10.	Compliance packaging	(18 VAC 110-20-10)
11.	Prescription drug	(21 USC 353(b))
12.	Nonprescription drug	(21 CFR 330)
13.	New drug	(21 USC 321(p))
14.	Investigational new drug	(21 CFR 312.3(b))
15.	US Pharmacopoeia drugs	(21 USC 321)
16.	Veterinary pharmaceuticals	(21 USC 353(f))

B. ASSURE AND MAINTAIN INTEGRITY OF DRUG PRODUCT

1. Evaluate drugs to determine whether they meet all legal requirements for selling, distributing, or dispensing (54.1-3461, 54.1-3462)
2. Recognize the conditions under which drugs are adulterated or misbranded while being held for dispensing (54.1-3461, 54.1-3462)
3. Identify and separate expired drugs (18 VAC 110-20-200(D))

C. ACCEPT OR DENY THE RETURN OF DRUGS AND DRUG DEVICES

1. Explain the conditions under which drugs and devices previously dispensed may be accepted for return to stock for resale (18 VAC 110-20-400), 54.1-3411.1

D. REPACKAGE AND LABEL PRESCRIPTION DRUGS

1. Explain labeling requirements for repackaged drugs (18 VAC 110-20-355(B))
2. Define appropriate expiration date for repackaged product (18 VAC 110-20-355(B))
3. Explain records required for reconstitution, bulk compounding, and repackaged drugs (18 VAC 110-20-355 (A))

IV. MAINTAIN SECURITY OF DRUGS AND DEVICES

A. RESTRICT ACCESS AND MAINTAIN PROPER STORAGE AND SECURITY OF ALL SCHEDULE II THROUGH VI DRUGS AND DEVICES

1. Explain who may have access to the prescription department while the pharmacist is on duty (18 VAC 110-20-190(C))
2. Identify security options for the storage of Schedule II-VI controlled drugs (18 VAC 110-20-180, 18 VAC 110-20-200)
3. Explain the requirements for an alarm system and when it should be activated (18 VAC 110-20-180)
4. Explain requirements for maintaining restricted access to the prescription department in the absence of the pharmacist (18 VAC 110-20-190(A-B))
    a. Define prescription department (18 VAC 110-20-10)
5. Explain appropriate storage for prescriptions awaiting delivery (18 VAC 110-20-200(A))
6. Describe the methods for storing Schedule II drugs within the prescription department (18 VAC 110-20-200(B))
7. Explain secure storage of controlled paraphernalia (18 VAC 110-20-200(C))
8. Explain proper storage of expired drugs (18 VAC 110-20-200(D))
9. Explain proper storage of drugs stored outside of the pharmacy, in a hospital, or long-term care facility in a unit dose system (18 VAC 110-20-420(A)(1))
10. Explain the responsibilities of the pharmacist-in-charge for drug storage and security throughout hospitals and in long-term care facilities (18 VAC 110-20-440(A), 18 VAC 110-20-530(3-6))
11. Explain requirements and documentation for managing after-hours access to the pharmacy in a hospital (18 VAC 110-20-450)
12. Explain the security requirements for drugs in the emergency department of a hospital (18 VAC 110-20-470)
13. Explain the security requirements and documentation for drugs dispensed in CEMT kits, emergency drug kit, and stat drug boxes (18 VAC 110-20-500, 18 VAC 110-20-540, 18 VAC 110-20-550, 18 VAC 110-20-590(4))

B. REPORT STOLEN OR LOST DRUGS

1. Explain the reporting requirements for theft or loss of Schedule II-V drugs (54.1-3404(E))
    a. Explain reporting requirements required by the DEA (21 CFR 1301.76)
2. Explain the conditions under which an inventory needs to be taken following a drug loss (54.1-3404(E))
3. Describe record keeping requirements for loss of drugs (54.1-3404(E-F))

V. REVIEW PRESCRIPTIONS

A. RECEIVE PRESCRIPTIONS AND ORDERS

1. Describe the general requirements for receipt and documentation of verbal prescriptions (54.1-3410(B), 54.1-3410(D), 54.1-3411, 18 VAC 110-20-470(2), 18 VAC 110-20-500(3), 18 VAC 110-20-540(5), 19 VAC 110-20-550(3), 18 VAC 110-20-420 (A) (2), 54.1-3320 (2))
2. Describe the requirements for receipt and documentation of oral prescriptions for Schedule II drugs (54.1-3410(A2), 18 VAC 110-20-290)
3. Describe conditions under which a prescription may be faxed and documentation required (18 VAC 110-20-280)
4. Explain the requirements for transferring prescriptions between pharmacies (18 VAC 110-20-360, 18 VAC 110-20-370)

a. Explain the limitation for transferring a prescription for Schedule III-V drugs for refill purposes (21 CFR 1306.25)

5. Explain the requirements for obtaining, recording, and maintaining patient information (54.1-3319(D))

B. REVIEW PRESCRIPTION ORDERS

1. Review prescriptions for legality

   a. Assure that prescriptions are written in good faith within the context of a bona fide physician-patient relationship for a medicinal or therapeutic purpose (54.1-3303(A-B), 54.1-3408.01, 54.1-3408.03)

   b. Determine whether a prescription is written within a prescriber's authority and scope of practice (54.1-3303(A-E))

   c. List which health care practitioners have prescriptive authority in Virginia (54.1-3303(A, D, E, F), 54.1-3408, 54.1-3401)

   d. Describe the conditions under which an out-of-state prescription may be filled (54.1-3303(C))

   e. Discuss the limitations upon accepting prescriptions from medical interns or residents and the purpose of the suffix assigned to the intern or resident for prescribing Schedule II-V controlled substances (18 VAC 100-20-510)

   f. Describe the method for handling prescriptions that are declined for reasons other than nonavailability of the drug (18 VAC 110-20-270(D))

   g. Describe the requirements for ensuring the legality of questionable prescriptions (54.1-3303(B))

   h. Evaluate prescription forms used by medical interns or residents in a hospital (18 VAC 110-20-510)

   i. Identify the schedules of commonly used drugs as listed in Appendix A

   j. Explain the federal regulations governing exemptions from classification as Schedule II-V controlled substances (21 CFR 1308)

   k. Explain the criteria used for the general classification of Schedule I-V drugs (54.1-3443(A), 21 USC 811(c))

   l. Explain the allowances and limitations for dispensing drugs for maintenance and detoxification of narcotic addiction outside of a treatment program (21 CFR 1306.07)

2. Review prescriptions for required elements

   a. Describe the information that must appear on any prescription (54.1-3408.01, 54.1-3408.03, 54.1-3409, 54.1-3410,)

   b. Describe the additional information required on a faxed prescription (18 VAC 110-20-280(A)(3))

   c. Identify any additional information required for a valid prescription for a Schedule II-V drug (DEA # etc.) (21 CFR 1306.05)

3. Conduct drug use reviews

   a. Describe the requirements for conducting a prospective drug review prior to dispensing (54.1-3319(A))

   b. Describe the requirements for performing monthly reviews of drug therapy for patients in a hospital or LTC facility (18 VAC 110-20-440(B), 18 VAC 110-20-530(9))

VI. DISPENSING AND DISTRIBUTION

A. DISPENSING DRUGS PURSUANT TO A PRESCRIPTION

1. Terminology

a.	Personal supervision	(18 VAC 110-20-10)
b.	Repackaged drug	(18 VAC 110-20-10)
c.	Safety closure container	(18 VAC 110-20-10)
d.	Special packaging	(18 VAC 110-20-10)
e.	Terminally ill	(18 VAC 110-20-10)
f.	Compounding	(54.1-3401)
g.	Device	(54.1-3401)
h.	Dispense	(54.1-3401)
i.	Drug	(54.1-3401)
j.	Administer	(54.1-3401)
k.	Label	(54.1-3401)
l.	Labeling	(54.1-3401)
m.	Prescription	(54.1-3401)
n.	Schedule VI device	(54.1-3455)
o.	Schedule VI	(54.1-3455)
p.	Controlled substance	(54.1-3401)
q.	Controlled substance	(21 USC 802(6))
r.	Drug sample	(21 USC 353)

2. Explain the conditions under which prescriptions for Schedule II drugs may be filled to include time limitations and conditions for partially filling (54.1-3410(A)(1-2), 54.1-3411(1), 18 VAC 110-20-290, 18 VAC 110-20-310)

    a. Describe the records required for dispensing Schedule II drugs and methods of filing (54.1-3404(D, F), 54.1-3412, 18 VAC 110-20-240(B)(1-2), 18 VAC 110-20-250)

3. Explain the conditions under which prescriptions for Schedule III-V drugs may be filled or refilled to include time limitations, restrictions, and requirements for partial filling (54.1-3410(B), 54.1-3411(2), 18 VAC 110-20-320(A,D))

    a. Describe the records required for dispensing Schedule III-V drugs and methods of filing (54.1-3404(D, F), 54.1-3412, 18 VAC 110-20-240(B)(1-3), 18 VAC 110-20-250, 18 VAC 110-20-320(C))

4. Explain the conditions under which prescriptions for Schedule VI drugs may be filled or refilled to include time limitations. (54.1-3410(B, C), 54.1-3411(2,3,4) 18 VAC 110-20-320(B,D))

    a. Describe the records required for dispensing Schedule VI drugs and methods of filing (54.1-3410, 54.1-3412, 18 VAC 110-20-320(C), 18 VAC 110-20-240(B) (3), 18 VAC 110-20-250)

5. Explain how to properly package prescriptions (54.1-3426, 54.1-3427, 18 VAC 110-20-340, 18 VAC 110-20-350)

6. Explain how to properly label prescriptions (54.1-3410 (A) (3) & (B) (2), 54.1-3463(A), 18 VAC 110-20-330)

    a. Explain caution label requirement for Schedule II-V drugs (21 CFR 290.5)

    b. Explain additional labeling required when dispensing products containing estrogen (21 CFR 310.515)

7. Explain requirements for making an offer to counsel and describe the components of counseling (54.1-3319(B-E))

8. Explain requirements for compounding (54.1-3401, 54.1-3410.2, 18 VAC 110-20-411 – 416)

B. DISPENSE DRUGS USING A UNIT DOSE DISPENSING SYSTEM FOR A HOSPITAL OR LONG-TERM CARE FACILITY

1. Explain packaging, labeling, and record keeping requirements for a unit-dose-system (18 VAC 110-20-420)
2. Distinguish between the requirements for a unit dose system in facilities where licensed individuals administer drugs versus facilities where unlicensed individuals administer drugs (18 VAC 110-20-420)
3. Set forth the labeling requirements for drugs dispensed in a unit dose system (18 VAC 110-20-420)

C. DISPENSING OR DISTRIBUTION BY OTHER METHODS

1. Explain procedures and required records for dispensing floor stock drugs in a hospital unit (18 VAC 110-20-460)
2. Explain procedures and required records for dispensing drugs from mechanical devices (18 VAC 110-20-490)
3. Explain the conditions under which insulin can be dispensed (54.1-3419)
4. Describe the conditions and documentation for sale of controlled paraphernalia (54.1-3467, 54.1-3468, 54.1-3469)
5. Explain the conditions and documentation for dispensing Schedule V drugs without a prescription (54.1-3416)
6. Describe types and conditions under which drugs may be floor-stocked or kept in an emergency box or stat drug box in a LTCF (18 VAC 110-20-540, 18 VAC 110-20-550, 18 VAC 110-20-560)

D. DISPENSING DEVICES

1. Explain the classification system for medical devices (21 USC 360)

APPENDIX A

The sections of Virginia law listing drugs within the various schedules are confusing and typically include legal or chemical names. For this reason, Appendix A was developed to assist you in studying this portion of the law for the examination. Appendix A is a listing of drug schedules and some generic and brand names of commonly dispensed drugs in each schedule. Drug names included in the examination, which require or test for knowledge of drug schedule, will be taken from this list.

SCHEDULE I:

Schedule I drugs are drugs which have a high potential for abuse, but which have no accepted medical use in treatment in the United Stated or which lack accepted safety for use in treatment even under medical supervision.

SCHEDULE II:

GENERIC NAME	***SOME BRAND NAMES***
meperidine	Demerol
morphine sulfate	M.S. Contin, Roxanol
oxycodone	Percodan, Percocet, Tylox
hydromorphone	Dilaudid
methadone	Dolophine
codeine (as a single drug entity)	
fentanyl	Sublimaze
alfentanyl	Alfenta
sufentanil	Sufenta
opium	
cocaine	
methylphenidate	Ritalin
amphetamine	Biphetamine
dextroamphetamine	Dexedrine
phenmetrazine	
methamphetamine	Desoxyn
pentobarbital (suppositories are schedule III)	Nembutal
secobarbital (suppositories are schedule III)	Seconal
amobarbital (suppositories are schedule III)	Amytal

SCHEDULE III:

GENERIC NAME	*SOME BRAND NAMES*
codeine in combination with acetaminophen	Tylenol with codeine #2, #3, #4; Phenaphen with codeine #2, #3, #4
codeine in combination with aspirin	Empirin with codeine #2, #3, #4
hydrocodone	Tussionex, Vicodin, Lorcet Plus, Lortab, Hycodan, Zydone, Anexsia
butabarbital	Butisol
butalbital (unless in combination with acetaminophen, then schedule VI)	Fiorinal, Fiorinal with codeine
thiopental sodium	Pentothal
benzphetamine	Didrex
phendimetrazine	Bontril, Prelu-2
nandrolone	Anabolin, Androlone, Deca-Durabolin, Durabolin, Hybolin, Nandrobolic
stanozolol	Winstrol
oxandrolone	Anavar

SCHEDULE IV:

GENERIC NAME	*SOME BRAND NAMES*
diazepam	Valium
lorazepam	Ativan
alprazolam	Xanax
chlordiazepoxide	Librium
oxazepam	Serax
prazepam	Centrax
triazolam	Halcion
clonazepam	Klonopin
chlorazepate	Tranxene
flurazepam	Dalmane
zolpidem	Ambien
temazepam	Restoril
phenobarbital	
pentazocine	Talwin

propoxyphene	Darvon
phentermine	Fastin, Ionamin, Adipex-P
diethylproprion	Tepanil, Tenuate
fenfluramine	Pondimin
mazindol	Sanorex

SCHEDULE V:

GENERIC NAME	*SOME BRAND NAMES*
most cough syrups containing codeine	
diphenoxylate	Lomotil

SCHEDULE VI:

All prescription drugs and devices which have not been placed in another schedule are in Schedule VI. This includes any drug or device which is not in another schedule, but which is required by federal law to bear on its label one of the following legends:

1. "R_x only" or "Caution: Federal Law Prohibits Dispensing Without Prescription"

2. "Caution: Federal Law Restricts This Device To Sales By Or Use On The Order Of A Physician"

3. "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian"

Schedule VI also includes any drug not listed in Schedules I - V which because of toxicity, potential for harm, method of use, or collateral measures necessary to its use is not generally recognized among experts as being safe for use except by or under the supervision of a practitioner licensed to prescribe.

APPENDIX B

I

U.S. CODE TITLE 21 FOOD AND DRUGS
UNITED STATES CODE:
http://www.gpoaccess.gov/uscode/index.html
(Use the Browse feature)

CHAPTER 9 – FEDERAL FOOD, DRUG AND COSMETIC ACT

321	Definitions, generally
351	Adulterated drugs and devices
352	Misbranded drugs and devices
353	Exemptions and considerations for certain drugs, devices and biological products
353a	Pharmacy compounding
360	Registration of producers of drugs or devices
360c	Classification of devices intended for human use
374	Inspection

CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL

802	Definitions
811	Authority and criteria for classification of substances
812	Schedules of controlled substances
823	Registration requirements
827	Records and reports of registrants
828	Order forms
829	Prescriptions

CODE OF FEDERAL REGULATIONS (CFR)
TITLE 21 CFR FOOD AND DRUGS
http://www.gpoaccess.gov/cfr/index.html
(Use the Browse feature)

CHAPTER 1

Part 290	Controlled drugs
Part 291	Drugs used for treatment of narcotic addicts
Part 310	New drugs
Part 330	Over-the-counter human drugs

CHAPTER 2

Part 1301	Registration of manufacturers, distributors and dispensers of controlled substances
Part 1302	Labeling and packaging for controlled substances
Part 1304	Records and reports of registrants
Part 1305	Order forms
Part 1306	Prescriptions
Part 1307	Miscellaneous
Part 1308	Schedules of controlled substances
Part 1316	Administrative functions, practices, and procedures

THE PHARMACIST'S MANUAL
(from the United States Drug Enforcement Agency Diversion Control Program)
http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm